

CLAIMS:

1. A hollow radially expandable balloon member (1, 63) having terminal portions (7, 8) which have a diameter smaller than the intermediate portion (9) intermediate the terminal portions (7, 8) and having a fluid impervious wall (2, 3), which balloon member (1, 63) is for use with a catheter (61) for radially expanding a vessel in the body of a mammal, which catheter comprises a tube portion (61) with a passage therethrough and which is adapted to have the hollow expandable balloon member (63) secured to the tube portion (61) by the smaller diameter terminal portions (7, 8), whereby the balloon member (63) can be inflated and deflated by means of a fluid passed through the passage of the catheter (61), characterised in that:
- a. the wall of the balloon member (1) has a substantially uniform thickness and is formed from a flexible substantially fluid impervious material (2) having reinforcing fibres (3) provided integrally with the wall material (2), which fibres (3) act to limit the maximum radial expansion of the balloon member (1); and
  - b. the intermediate larger diameter portion (9) of the balloon member (1) being preformed with a radial diameter which corresponds substantially to that of the balloon member (1) at a maximum unstretched radially expanded state, whereby the balloon member (1) can be inflated to its maximum radial expansion state as limited by the fibres (3) within the wall material (2) without causing substantial stretching the wall material (2).
2. A balloon member (1) as claimed in claim 1, characterised in that the reinforcing fibres (3) are provided by a polymer or metal mesh.
3. A balloon member (1) as claimed in claim 1, characterised in that the reinforcing fibres (3) are made from or contain a material (110) having shape memory properties.

4. A balloon member (1) as claimed in claim 1, characterised in that the reinforcing fibres (3) are provided as a braid of filaments of a metal or polymeric material.
5. A balloon member as claimed in claim 1, characterised in that the reinforcing fibres are filaments of a polyester polymer.
6. A balloon member (1) as claimed in claim 4, characterised in that the braid (3) is in the form of two opposed helices of filaments.
7. A balloon member (1) as claimed in claim 6, characterised in that the opposed helices (3) are orientated to one another at or adjacent to the critical angle of the braid.
8. A balloon member (1) as claimed in claim 1, characterised in that the reinforcing fibres (3) limit the maximum radial expansion of the wider diameter portion (9) of the balloon member (1) to not more than 115% of its maximum unstretched radially expanded state.
9. A balloon member (1) as claimed in <sup>claim 1</sup> ~~any one of the preceding claims~~, characterised in that the flexible wall material (2) is a polyurethane.
10. A balloon member (63) for use with a catheter tube (61) as claimed in <sup>claim 1</sup> ~~any one of the preceding claims~~ substantially as hereinbefore described with respect to and as shown in any one of the accompanying drawings.
11. A balloon catheter (61, 63) for radially expanding a vessel in the body of a mammal, which catheter comprises a tube portion (61) with a passage therethrough and a hollow expandable balloon portion (63) defined by a fluid impervious wall (2, 3) and secured to the tube portion (61), which balloon portion (63) can be inflated and

a deflated by means of a fluid passed through the passage (61), characterised in that the balloon portion (63) is a balloon member (1) as claimed in <sup>claim 1</sup> ~~any one of claims 1 to 10.~~

12. A method of manufacturing a balloon member (1) as claimed in claim 1, which method is characterised in that it comprises;

- a. forming a generally tubular member (1) having a wall of substantially uniform thickness and formed from a flexible substantially fluid impervious material (2) having reinforcing fibres (3) provided integrally with the wall material (2), which fibres (3) act to limit the maximum radial expansion of the balloon member (1), the tubular member (1) having an external diameter which corresponds substantially to that desired for the balloon member (1) in its maximum radial expansion state;
- b) stretching the tubular member (1) axially until the inner diameter of the tubular member (1) adjacent the terminal portions (7, 8) thereof is reduced to or proximate to the external diameter of the catheter tube (61) upon which it is desired to mount the balloon member (1,63);
- c) applying a process to at least one of the terminal portions (7 or 8) of the axially stretched tubular member (1) in order to set the reduced inner diameter of that terminal portion (7 or 8) of the stretched tubular member (1); and
- d) relieving the axial stretch of the tubular member (1) in order to allow the portion (9) of the tubular member (1) intermediate the terminal portions (7, 8) to expand radially to provide the wider diameter intermediate portion (9) of the balloon member (1).

13. A method as claimed in Claim 12, characterised in that the process for setting the terminal portion (7 or 8) of the tubular member (1) comprises heating the terminal portion (7 or 8).

14. A method as claimed in Claim 12, in which at least the terminal portions (7, 8) of the tubular member (1) comprise a partially cured polymer, and the process for

fixing the terminal portion (7 or 8) of the tubular member (1) comprises causing further polymerisation of the partially cured polymer.

15. A method of manufacturing a balloon member (1) for a balloon catheter (61, 63), substantially as herein described, with reference to and as shown in any one of the accompanying drawings.